



Centre for Applied Microbiology and Research  
and  
European Collection of Cell Cultures

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This document certifies that  
Hybridoma LM04 20F8.B2.C8  
Deposit Reference 03052002

has been accepted as a patent deposit, in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on  
20 May 2003

  
Dr D H Lewis  
General Manager  
ECACC

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO  
DR L WILSON  
WALTER & ELISA HALL INSTITUTE OF ME

INTERNATIONAL FORM

POST OFFICE  
ROYAL MELBOURNE HOSPITAL  
PARKVILLE  
VIC 3050  
AUSTRALIA

NAME AND ADDRESS  
OF DEPOSITOR

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

LMO4 20F8.B2.C8

Accession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:

03052002

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:



A scientific description



A proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on 20 May 2003 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depository Authority on (date of the original deposit) and  
A request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC  
CAMR  
Porton Down  
Salisbury SP4 0JG

Signature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized officials(s):

Date:

16/3/04

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO  
DR L WILSON  
WALTER & ELISA HALL INSTITUTE OF ME

POST OFFICE  
ROYAL MELBOURNE HOSPITAL  
PARKVILLE  
VIC 3050  
AUSTRALIA

VIABILITY STATEMENT  
Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

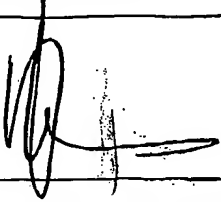
NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>Name: DR L WILSON WALTER &amp; ELISA HALL INSTITUTE OF ME</p> <p>Address: POST OFFICE ROYAL MELBOURNE HOSPITAL PARKVILLE VIC 3050 AUSTRALIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  03052002</p> <p>Date of the deposit or of the transfer:  20 May 2003</p>
II. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on 20 May 2003<sup>1</sup>. On that date, the said microorganism was</p> <p><input checked="" type="checkbox"/> , viable</p> <p><input type="checkbox"/> , no longer viable</p>	

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.

- 3 Mark with a cross the applicable box.

Form BP/4 (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>		
II. INTERNATIONAL DEPOSITARY AUTHORITY		
Name:	Dr D H Lewis	
	ECACC CAMR	
Address:	Porton Down	
	Salisbury	
	Wiltshire	
	SP4 0JG	
		Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):
		Date: 16/3/04

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

## Certificate of Analysis

Product Description  
Lot Number

LM04 20F8.B2.C8  
03/K/012

Test Description: Cell Count, Viability and confluency of cells on resuscitation from frozen.

Acceptance Criterion/Specification: were judged acceptable if they meet two of the following criteria:

- >70% viable cells
- $>2 \times 10^6$  viable cells/ml
- confluent in 2 days

Date: 09/01/04  
Result:

Viable Cell Count:  $1.02 \times 10^7$  cells/ml  
Percentage Viability: 57%  
Confluent in: Good Growth in 2 days

Test Description: The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01

Acceptance Criterion/Specification: All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.

The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.

Test Number: 28716  
Date: 09/02/04  
Result:

Positive Control: Positive  
Negative Control: Negative  
Test Result: Negative  
Overall Result: PASS

Authorised by Chloe Wilson Acting ECACC, Head of Quality... 18/12/04 Date

## Certificate of Analysis

Product Description      LM04 20F8.B2.C8  
Lot Number                03/K/012

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Test Description:      Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07

Acceptance Criterion/Specification: The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

Test Number: 28716  
Date: 19/01/04  
Result:  
Positive Control: Positive  
Negative Control: Negative  
Test Result: Negative  
Overall Result: PASS

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Test Description:      Sterility Testing of Cell Banks (SOP ECACC/048)

Acceptance Criterion/Specification: All positive controls (*Bacillus subtilis* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

Test Number: 28716  
Date: 12/12/03  
Result:  
Positive Control: Positive  
Negative Control: Negative  
Test Result: Negative  
Overall Result: PASS

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Test Description:      Monoclonal Antibody Isotyping.  
SOP ECACC/019

Acceptance Criterion/Specification: The light chain and isotype detected match those expected. A band appears in the positive control region.

Test Number: 28716  
Date: 22/01/04  
Result:  
Positive Control: Positive  
Expected Result: Unknown  
Test Result: IgG2a

Authorised by: *Ch. Carlson* Acting ECACC, Head of Quality. 15/2/04 Date